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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,317	09/17/2003	Jeffery D. Snell	A03P1064	6211

36802 7590 09/18/2006

PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER	
KAHELIN, MICHAEL WILLIAM	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/665,317	SNELL ET AL.	
	Examiner	Art Unit	
	Michael Kahelin	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20060818*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 3, 7-9, 12, 16, 18, 19, and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Yonce et al. (US 2003/0083711, hereinafter "Yonce").

3. In regards to claims 7, 18, and 21, Yonce discloses a method/device that acquires a plurality of ensemble averages of intracardiac ECG signals (Fig. 6, each tracing is an ensemble average per par. 0042); processing the plurality of averages to generate a model of cardiac activity (i.e. the model is the entire graph shown in Figure 6); wherein processing comprises detecting an evoked response within each ensemble average (par. 0027) using a level in the sensing channel (par. 0023).

4. In regards to claim 3, acquiring comprises acquiring a signal continuously and splitting the signal into the plurality of signals (Fig. 5).

5. In regards to claims 8 and 9, the evoked response may be detected in the atria or ventricles (par. 0005).

6. In regards to claims 12 and 13, the repeating occurs for at least 5 times (par. 0042) and 10-100 times (i.e. 5 times each for 3 templates is 15 times).

7. In regards to claims 16 and 19, an intracardiac ECG is compared to the ensemble average (abstract).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marcovecchio (US 2002/0032469, hereinafter "Marcovecchio") in view of Greenspon et al. (US 5,954,661, hereinafter "Greenspon"). Marcovecchio discloses the essential features of the claimed invention, but does not teach acquiring signals indicative of an

evoked response. Greenspon teaches acquiring and ensemble averaging the to increase the signal-to-noise ratio (see column 10, lines 51-60). Therefore, it would have been obvious to one skilled in the art at the time the invention was disclosed to combine the detecting of QRS-complexes and averaging them to determine whether a tachycardia has occurred with detecting an evoked response in order to increase the signal-to-noise ratio.

11. Claims 4-6, 10, 11, 14, 15 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yonce in view of Stoop et al. (US 2001/0007948, hereinafter "Stoop"). Yonce discloses the essential features of the claimed invention except for generating a histogram based on the ensemble averages that represent counts versus time, counts versus amplitude, ventricular and/or atrial events with respect to time, or ventricular and/or atrial events with respect to amplitude; using a histogram to alter therapy; or analyzing the histogram to characterize cardiac function as normal or abnormal. Stoop teaches of providing an implantable pacemaker with a means for generating a histogram based on ensemble averages that represent counts versus time and counts versus amplitude (par. 0008), ventricular and/or atrial events with respect to time, or ventricular and/or atrial events with respect to amplitude (QT is a property of both atrium and ventricle) to determine abnormal heart function based on various parameters' deviation from typical values specific to a patient; using a histogram to alter therapy (par. 0008) to adjust therapy based on values specific to a patient; and analyzing the histogram to characterize cardiac function as normal or abnormal (i.e. if the decision is made to apply therapy, abnormal function has been determined) to

provide a diagnosis based on a particular patient's heart's deviation from normal function. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Yonce's invention with means for generating a histogram based on ensemble averages that represent counts versus time and counts versus amplitude, ventricular and/or atrial events with respect to time, or ventricular and/or atrial events with respect to amplitude to determine abnormal heart function based on various parameters' deviation from typical values specific to a patient; using a histogram to alter therapy to adjust therapy based on values specific to a patient; and analyzing the histogram to characterize cardiac function as normal or abnormal to provide a diagnosis based on a particular patient's heart's deviation from normal function.

Response to Arguments

12. Applicant's arguments filed 7/6/2006 have been fully considered but they are not persuasive. Applicant argued that the combination of Marcovecchio and Greenspon is both lacking motivation to combine and would render Marcovecchio's invention inoperable. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re*

Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, as indicated in the last Office Action, utilization of the evoked response in the ensemble averages will increase the signal-to-noise ratio. This is based on the notoriously well-known fact that the waveforms of intrinsic and evoked responses appear vastly different on an ECG tracing. Additionally, Greenspon indicates that the disclosed method can identify VT in a patient without actually invoking VT (col. 3, line 10). These teachings of Greenspon indicate that using the evoked response to construct the ensemble averages will increase the signal-to-noise ratio by virtue of recognizing that a measured evoked response is a fundamentally different signal and not just a noisy intrinsic signal (as Marcovecchio's invention would as it does not distinguish between intrinsic and evoked cardiac signals). Greenspon's second teaching (i.e. col. 3, line 10) provides motivation to a skilled artisan to modify Marcovecchio's invention by utilizing evoked response because the evoked response VT detection of Greenspon does not require tachycardia to be present to make the diagnosis, but only slow conduction in the myocardium. Marcovecchio's invention will not detect tachycardia until it is symptomatic (i.e. tachy-related complexes are present).

13. In response to applicant's argument that the combination of Greenspon and Marcovecchio would be inoperable, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references

would have suggested to those of ordinary skill in the art, as elaborated above. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK
9/12/06

GEORGE R. EVANISKO
PRIMARY EXAMINER
9/14/6